



UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/544,773	04/07/00	REYES	0229 1047

002292 HM22/1003
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH VA 22040-0747

EXAMINER
MYERS, C

ART UNIT	PAPER NUMBER
1001	

DATE MAILED: 10/03/01 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/544,773

Applicant(s)

REYES ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. This action is in response to Paper No. 9, filed July 2, 2001. This action contains new grounds of rejection and is made non-final.
2. The terminal disclaimer filed on July 2, 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,027,923 has been reviewed and is accepted. The terminal disclaimer has been recorded.
3. The specification is objected to because the assigned SEQ ID NOS have not been used to identify each sequence listed in the specification, as required under 37 CFR §1.821(d). The specification must be amended to recite the appropriate sequence identifier next to each sequence recited.
4. The disclosure is objected to because of the following informalities:

In claim 5, "claims 1" should be amended to read "claim 1".

In claim 5, line 4, "primes" should be amended to read "primers".
5. Claim 2-15 and 17-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-15 are indefinite over the recitation of "the sequence of the nucleic acid sequence of interest" and "the sequence of interest" because these phrases lack proper antecedent basis.

Claims 2 and 6-15 are indefinite over the recitation of "primers of step (b)". Because claims 2 and 6-15 depend from claim 1, the claims contain 2 step (b)'s. Accordingly, it is unclear as to what is intended to be encompassed by the "primers of step (b)".

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Claims 2 and 6-15 are indefinite and confusing over the recitation of “the primer for the first strand” and “said primers for producing said first generation primer extension product” because these phrases lack proper antecedent basis and it is unclear as to whether the primers set forth in claims 2 and 6-15 are distinct from or the same as the first and second primers of claim 1.

Claims 3 and 6-15 are indefinite and confusing over the recitation of “said first and second primers containing a non-replicable element and/or a cleavable element”. The claims previously define the first and second primers as including a non-replicable element (see claim 1), yet this recitation infers that the non-replicable element need not be present in the first and second primers. Accordingly, it is unclear as to whether the first and second primers set forth in claims 3 and 6-15 are considered to be the same as or distinct from the first and second primers set forth in claim 1.

In claims 4, 6-15, 19 and 21-30, step (c), the phrase “this step” lacks proper antecedent basis and it is unclear as to what “this step” is intended to refer to.

In claim 4, 6-15, 19 and 21-30, step (c), the phrase, “said strand” lacks proper antecedent basis because the claim previously refers to a first and second strand and it is unclear as to whether “said strand” refers to either or both of the first and second strands.

In claims 4, 6-15, 19 and 21-30, step (h), the phrase “the step” lacks proper antecedent basis because the claim previously refers to several different steps. The claim should be amended to refer to “step (g)”.

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Claims 4-15 are indefinite over the recitation in claims 4 and 5, line 4, of “each primer”. This phrase is unclear because the claims previously refer to a first and second primer and to nested primers. The claims should be amended to refer to “each nested primers”. ✓

Claims 4-15 are indefinite over the recitation of “said first primers are primers of said nested primers” because it is not clear as to what is intended to be meant by this phrase. It is unclear as to whether these “first primers” are identical to or distinct from the primers of claim 1.

Claims 8 and 23 are indefinite over the recitation of “said primer” because it is not clear as to whether this refers to the first primer, the second primer or the nested primers. If the claim intends to refer to the first or second primers, the claim is further indefinite over the recitation of “said primer contains a non-replicable element” because claim 1 already previously requires that the primer contains a non-replicable element and thereby it is unclear as to how this phrase is intended to further limit the claims.

Claims 9-11 and 24-26 are indefinite over the recitation of “said primer” because it is not clear as to whether this refers to the first primer, the second primer or the nested primers.

Claim 17 is indefinite over the recitation of “said strands” because this phrase lacks proper antecedent basis. The claim previously refers to “a first strand cDNA product”, but does not previously refer to “strands”.

Claim 17 is indefinite and confusing over the recitation of “said primers of step (b)” because the claim previously refers to only a “primer” and not to “primers”. Also, because claim

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17 depends from claim 16, claim 17 contains two step (b)'s and therefore it is unclear as to what is intended to be encompassed by "said primers of step (b)".

Claims 17-30 are indefinite over the recitation of "the sequence of the nucleic acid sequence of interest" and "the sequence of interest" because these phrases lack proper antecedent basis.

Claims 19-30 are indefinite over the recitation of "each primer". This phrase is unclear because the claims previously refer to a first and second primer and to nested primers. The claims should be amended to refer to "each nested primers".

Claims 19-30 are indefinite over the recitation of "said first primers are primers of said nested primers" because it is not clear as to what is intended to be meant by this phrase. It is unclear as to whether these "first primers" are identical to or distinct from the primers of claim 1.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 6-13, 16-18 and 21-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Newton et al (U.S. Patent No. 5,525,494).

Newton (see, for example, col. 2-3) teaches a method for amplifying a target nucleic acid wherein the method comprises contacting a sample nucleic acid, together or sequentially, with a

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first primer comprising a target binding region and a polynucleotide tail and with an amplification primer comprising a target binding region and a polynucleotide tail, in the presence of a polymerization agent under conditions in which the first primer and amplification primer anneal to the target nucleic acid and wherein the first primer and the amplification primer are extended to generate an amplification product. The first primer and the amplification primer each contain a polymerization blocking moiety positioned between the target binding region and the tail. In particular, "the first primer may be subjected to primer extension whereby a first primer extension product is synthesized based on the target nucleotide sequence as template, and after denaturation of the first primer extension product from its template and hybridization of the amplification primer to the desired portion of the first primer extension product, primer extension may be effected to form an amplification primer extension product, the presence of the first primer in the first primer extension product being effective to inhibit formation of a sequence complementary to the polynucleotide tail in the amplification primer extension product" (see col. 2, lines 36-48). Similarly, the presence of the amplification primer in the amplification primer extension product is effective to inhibit the formation of a sequence complementary to the polynucleotide tail of the primer extension product. Accordingly, Newton teaches amplification methods utilizing a first and second primer comprising a "non-replicable element". Newton teaches that the target sequence may be RNA or DNA (col. 6, lines 20-24) and teaches that the agent for polymerization may be any suitable DNA polymerase or reverse transcriptase (see col. 6, lines 44-51). The method of annealing primers to the template and separating the primer extension products from

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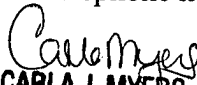
their templates may be repeated as many times as necessary to obtain the desired level of sequence amplification (col. 2). Thereby, Newton teaches that the amplification method is one for synthesizing cDNA from an RNA template and for further amplifying cDNA amplification products. Newton (col. 9) teaches that the polymerization blocking moiety may be a deoxy ribofuranosyl naphthalene or ribofuranosyl naphthalene moiety, which are considered to be derivatives of a deoxyribonucleotide and derivatives of a ribonucleotide. The primers of Newton are considered to contain "cleavable elements" because all nucleotides present in the primers can be cleaved by some type of cleaving agent, such as a nuclease, ribonuclease, etc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers


CARLA J. MYERS
PRIMARY EXAMINER

October 1, 2001